510(K) SUMMARY

Submitted By

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Device Name

Trade or Proprietary Name: INFINITI CYP2C19 Assay

Common or Usual Name: Cytochrome P450 CYP2C19 Test

Regulations and Product Codes

Regulations: 21CFR§862.3360 Drug Metabolizing Enzyme Genotyping Systems
21CFR§862.2570 Instrumentation for Clinical Multiplex Test Systems

Classification: Class II

Product Codes: NTI Drug Metabolizing Enzyme Genotyping System
NSU Instrumentation for Clinical Multiplex Test Systems

Predicate Device

(a) INFINITI Warfarin Assay (k073014)
(b) AmpliChip CYP450 Microarray (k043576)

Device Description

The INFINITI CYP2C19 Assay is an *in vitro* diagnostic device which utilizes proprietary film-based microarray technology combined with process automation, reagent management, and software technology for the detection and genotyping of the 2C19 *2, *3, and *17 mutations in genomic deoxyribonucleic acid (DNA) obtained from EDTA-anticoagulated whole blood samples.

The INFINITI CYP2C19 Assay is comprised of the BioFilmChip™ Microarray, the Intellipac Reagent Module and the PCR Amplification Mix. The INFINITI CYP2C19 Assay should be run using the AutoGenomics INFINITI Analyzer.

The BioFilmChip Microarray consists of a polyester film coated with proprietary multi-layer components designed for DNA analysis. The layers have been designed to provide a versatile surface to enhance test performance. There can be up to 240 spots per microarray with each spot representing a different allele. The microarrays are designed to be assay specific.

The Intellipac Reagent Module contains up four reservoirs that house the test reagents and has an integrated memory chip. Information on the reagent such as lot number, expiration date and remaining tests, are archived in the memory.

The PCR Amplification Mix consists of the reagents needed for the PCR amplification step of the assay.

The INFINITI CYP2C19 Assay is based on the following processes:
(a) DNA extraction
(b) PCR amplification of purified DNA from human genomic DNA
(c) Labeling of the amplified product (allele specific primer extension)
(d) Hybridization of the labeled amplified product to a microarray by signature Tag/Capture probe hybridization under isothermal conditions.
(e) Scanning of the microarray
(f) Signal detection and analysis
Steps (c) through (f) are automated by the INFINITI Analyzer.

The INFINITI Analyzer automates the 2C19 assay and integrates all the discrete processes of sample (PCR amplicon) handling, reagent management, hybridization, detection, and results analysis. The assays are processed automatically and read by the built-in confocal microscope. Results are analyzed and presented as genotype calls.

Intended Use

The INFINITI CYP2C19 Assay is an *in vitro* diagnostic test for the identification of a patient's CYP450 2C19 genotype in genomic deoxyribonucleic acid (DNA) obtained from EDTA-anticoagulated whole blood samples. The INFINITI CYP2C19 Assay is a qualitative assay for use in clinical laboratories upon prescription by the attending physician.

Indication for Use

The INFINITI CYP2C19 Assay is indicated for use as an aid to clinicians in determining therapeutic strategy for therapeutics that are metabolized by the CYP450 2C19 gene product, specifically *2, *3, *17.

The INFINITI CYP2C19 Assay is not indicated to be used to predict drug response or non-response.

Substantial Equivalence

Table 1a and Table 1b provide a comparison of the INFINITI CYP2C19 Assay to the predicate devices. The comparison demonstrates that the INFINITI CYP2C19 Assay is substantially equivalent to the predicate devices.

Table 1a

Characteristics	Predicate INFINITI Warfarin Assay (k073014)	Subject Device INFINITI CYP2C19 Assay
Similarities		
DNA sequence	Detects specific DNA sequences through recognition of DNA targets	Same
Technology	Microarray-based genotyping test for simultaneous detection (multiplex system) of DNA sequences	Same
Specimen Type	Purified DNA from EDTA-anticoagulated whole blood sample	Same
Reaction Conditions	• Utilizes thermal cycling • Utilizes target DNA amplification • Reactions occur on a single biofilm microarray chip	Same
Assay Results	• Assay signal results are interpreted by a software program • Assay results are provided as genotype calls reported to the end user in a report format	Same
Instrumentation	INFINITI Analyzer	Same
Differences		
Target Genes	CYP4502C9 and VKORC1	CYP4502C19

Table 1b

Characteristics	Predicate	Subject Device
	AmpliChip CYP450 Microarray (k043576)	INFINITI CYP2C19 Assay
Similarities		
Indication for use	As an aid in determining therapeutic strategy and treatment dose for therapeutics that are metabolized by the CYP450 2C19 gene product.	As an aid in determining therapeutic strategy for therapeutics that are metabolized by the CYP450 2C19 gene product. Not intended to predict drug response or non-response
DNA sequence	Detects specific DNA sequences through recognition of DNA targets	Same
Specimen Type	Purified DNA from EDTA-anticoagulated whole blood sample	Same
Technology	Microarray-based genotyping test for simultaneous detection (multiplex system) of DNA sequences	Same
Reaction Conditions	• Utilizes thermal cycling • Utilizes target DNA amplification • Reactions occur on a single biofilm microarray chip	Same
Assay Results	• Assay signal results are interpreted by a software program • Assay results are provided as genotype calls reported to the end user in a report format	Same
Target Gene	CYP450 2C19	Same
Differences		
Target Gene Mutations	CYP450 2C19 *2 and *3	CYP450 2C19 *2, *3, and *17

Performance The following are performance characteristics of the INFINITI CYP2C19 Assay:

Analytical Specificity

Studies related to specificity were conducted during assay development. PCR primer specificity was determined by amplicon size on a gel and sequencing the amplicon. ASP primer specificity was determined by the correct calls made by the assay using known genomic samples. Capture probe specificity was determined by hybridizing different oligos and demonstrating that correct oligo hybridizes to the known spot.

Limit of Detection (analytical sensitivity)

The analytical sensitivity (Limit of Detection) of the INFINITI CYP2C19 Assay was assessed by analysis of whole blood samples at serial dilutions representing 500ng, 400ng, 200ng, 100ng, 50ng, 20ng, 10ng and 5ng DNA input (per test) to determine the lowest level of genomic DNA (ng input per test) that would give a ≥ 90% correct call rate of the allele with no incorrect calls.

The following whole blood samples were used in the LOD studies: *1/*1, *1/*2, *1/*3, *1/*17, *2/*2 and *2/*17. Sample genotype was determined by bi-directional sequencing.

Two extraction methods were used in the studies: Qiagen QIAamp DNA Blood Kit and the PSS Magtration System. The concentration and A_{260}/A_{280} were determined by spectrophotometry for the extracted DNA.

A total of 1,560 tests were completed for the LOD studies. A ≥ 90% correct call rate with no incorrect calls for the allele was obtained at DNA input levels from 400ng/test to 5ng/test. There was one incorrect call at the 5ng DNA input level. The incorrect call was probably due to the low DNA concentration, therefore, we are not recommending DNA input level at this low concentration.

The lowest detectable level for the INFINITI CYP2C19 Assay is **20ng DNA per test**. This is less than one-half (1/2) the recommended DNA input level of 50ng/test, and four times the level at which an incorrect call was made by the assay. We believe that establishing the lowest detectable level at 20ng DNA/test is conservative and should preclude an incorrect call.

Table 2 provides a summary of the LOD studies for the INFINITI CYP2C19 Assay.

Table 2 Limit of Detection

Genotype[a]	Sample ID	ngDNA input per test	Replicates tested	Correct calls	Incorrect calls	No calls	% correct calls 1st time run	95% One-sided Confidence Lower Limit
*1/*1	AG44 AG105 AG208 AG209 AG211 AG219	500	40	34	0	6	85.0%	72.7%
		400	40	38	0	2	95.0%	87.0%
		200	40	38	0	2	95.0%	87.0%
		100	40	40	0	0	100%	98.8%
		50	40	39	0	1	97.5%	91.4%
		20	40	39	0	1	97.5%	91.4%
		10	40	38	0	2	95.0%	87.0%
		5	40	39	0	1	97.5%	91.4%
	Total		**320**	**305**	**0**	**15**	**95.3%**	**92.8%**
*1/*2	AG81 AG197 AG210 AG223	500	20	19	0	1	95.0%	82.9%
		400	20	20	0	0	100%	97.5%
		200	20	20	0	0	100%	97.5%
		100	20	20	0	0	100%	97.5%
		50	40	37	0	3	92.5%	83.1%
		20	40	36	0	4	90.0%	79.5%
		10	40	38	0	2	95.0%	87.0%
		5	40	39	0	1	97.5%	91.4%
	Total		**240**	**229**	**0**	**11**	**95.4%**	**92.6%**
*2/*2	AG82 AG199 AG214 AG233	500	40	40	0	0	100%	98.8%
		400	40	39	0	1	97.5%	91.4%
		200	40	37	0	3	92.5%	83.1%
		100	40	39	0	1	97.5%	91.4%
		50	40	37	0	3	92.5%	83.1%
		20	40	38	0	2	95.0%	87.0%
		10	40	37	0	3	92.5%	83.1%
		5	40	37	0	3	92.5%	83.1%
	Total		**320**	**304**	**0**	**16**	**95.0%**	**92.5%**
*1/*3	AG152 AG162	500	40	40	0	0	100%	98.8%
		400	40	40	0	0	100%	98.8%
		200	40	40	0	0	100%	98.8%
		100	40	39	0	1	97.5%	91.4%
		50	40	40	0	0	100%	98.8%
		20	40	40	0	0	100%	98.8%
		10	40	40	0	0	100%	98.8%
		5	40	38	1	1	95.0%	87.0%
	Total		**320**	**317**	**1**	**2**	**99.1%**	**97.9%**

Genotype[a]	Sample ID	ngDNA input per test	Replicates tested	Correct calls	Incorrect calls	No calls	% correct calls 1st time run	95% One-sided Confidence Lower Limit
*1/*17	AG74 AG94 AG180 AG235	500	40	36	0	4	90.0%	79.5%
		400	40	38	0	2	95.0%	87.0%
		200	40	40	0	0	100%	98.8%
		100	40	40	0	0	100%	98.8%
		50	40	40	0	0	100%	98.8%
		20	40	38	0	2	95.0%	87.0%
		10	40	40	0	0	100%	98.8%
		5	40	39	0	1	97.5%	91.4%
	Total	**320**	**311**	**0**	**9**	**97.2%**	**95.2%**	**Total**
*2/*17	AG191 AG195	100	20	20	0	0	100%	97.5%
		5	20	20	0	0	100%	97.5%
	Total		**40**	**40**	**0**	**0**	**100%**	**98.8%**

a determined by bi-directional sequencing

Percent Agreement vs. Bi-directional Sequencing

The INFINITI CYP2C19 Assay was compared to bi-directional sequencing as the comparator method. Three sites were used for the comparison studies. Each site tested its own patient samples with the INFINITI CYP2C19 Assay. Patient samples were de-identified to protect patient's identity.

- A total of 317 samples were tested.
- There were no incorrect calls
- Six samples (1.9%) had to be repeated because of "no call" due to NTCE Error. NTCE is reported when the quality or quantity of the DNA in the sample/PCR product is poor. All six no calls gave correct calls upon the repeat for a 100% agreement of the INFINITI CYP2C19 Assay with bi-directional sequencing. The repeat test was done on the same extracted DNA. Only one repeat was done for each sample.

The results of the comparison studies comparing the INFINITI CYP2C19 Assay to bi-directional sequencing are provided in Table 3.

Table 3 Agreement between INFINITI CYP2C19 Assay with Bi-directional Sequencing

Genotype[a]	Number Tested	Replicates per Sample	Number of Correct Genotype Calls	Number of Incorrect Calls	No Calls	Agreement	95% One-sided Confidence Lower Limit
*1/*1	105	1	103	0	2	98.1%	95.0%
*1/*2	80	1	77	0	3	96.2%	91.5%
*2/*2	12	1	12	0	0	100%	95.8%
*1/*3	8	1	8	0	0	100%	93.8%
*3/*3	1	1	1	0	0	100%	50.0%
*1/*17	74	1	73	0	1	98.6%	95.3%
*17/*17	16	1	16	0	0	100%	96.9%
*2/*3	4	1	4	0	0	100%	87.5%
*2/*17	16	1	16	0	0	100%	96.9%
*3/*17	1	1	1	0	0	100%	50.0%
Total	317	1	311	0	6	98.1%	96.4%

a Genotype determined by bi-directional sequencing; *1/*1 samples are wild-type for *2, *3 and *17

Assay Inter-Laboratory Reproducibility

A three-site study was conducted to demonstrate the reproducibility of the INFINITI CYP2C19 Assay. The study involved three identical lots of the INFINITI CYP2C19 Assay, four operators, and four instruments (one site ran two sets of reproducibility studies, each with a different operator and instrument).

The sites ran identical samples comprised of 12 whole blood samples. The sites were blinded to sample identity. At each site, each sample was run in duplicate per day/operator for five non-consecutive days. A total of 430 tests were run. Of the 430 samples assayed, 14 samples (3.3%) had to be repeated due to "No Calls". The samples were repeated using the same extracted DNA. These NTCE errors might have been caused by temperature gradient during PCR, improper sealing of the PCR tubes, or operator pipetting error. The genotype calls from the repeat assays were 100% correct. There was one incorrect call (*1/*2 instead of *2/*2). The root cause of the incorrect call was not definitively determined.

Results of the inter-laboratory reproducibility study are summarized in Table 4a and Table 4b.

Table 4a Inter-Laboratory Reproducibility of the INFINITI CYP2C19 Assay by Genotype Call

Genotype[a]	Samples Tested	Site[b]	Replicates per Site	Replicates with Genotype Calls made by INFINITI[c]	Correct Calls	Incorrect Calls[d]	No Calls[e]	% Correct Calls[f]	95% One-sided Confidence Lower Limit
*1/*1	2	1	40	39	39	0	1	97.5	91.4
		2	20	20	20	0	0	100	97.5
		3[g]	10	10	10	0	0	100	95.0
		total	70	69	69	0	1	98.6	95.1
*1/*2	3	1[h]	40	40	40	0	0	100	98.8
		2	30	30	30	0	0	100	98.3
		3	30	30	30	0	0	100	98.3
		total	100	100	100	0	0	100	99.5
*2/*2	2	1	40	39	38	1	1	95.0	87.0
		2	20	20	20	0	0	100	97.5
		3	20	14	14	0	6	70.0	47.4
		total	80	73	72	1	7	90.0	82.8
*1/*3	1	1	20	20	20	0	0	100	97.5
		2	10	10	10	0	0	100	95.0
		3	10	10	10	0	0	100	95.0
		total	40	40	40	0	0	100	98.8
*1/*17	2	1	40	39	39	0	1	97.5	91.4
		2	20	17	17	0	3	85.0	66.9
		3[i]	10	9	9	0	1	90.0	66.4
		total	70	65	65	0	5	92.9	86.1
*17/*17	2	1	40	40	40	0	0	100	98.8
		2	20	19	19	0	1	95.0	82.9
		3[j]	10	10	10	0	0	100	95.0
		total	70	69	69	0	1	98.6	95.1
Total	**12**	**All**	**430**	**416**	**415**	**1[d]**	**14[e]**	**96.5**	**94.7**

[a] determined by bi-directional sequencing; *1/*1 samples are wild-type for *2, *3 and *17

[b] Internal site (Site 1) had two sets, one operator each

[c] Excludes samples with No Calls

[d] Initial result was incorrect (*1/*2 instead of *2/*2). The root cause of the incorrect call was not definitively determined.

[e] One no call was due to Registration Spot Error - this error is reported when the microarray chip is not properly aligned. Repeat test gave the correct call

13 reported NTCE Error - NTCE is reported if the quality or quantity of the DNA in the sample/PCR product is poor. Repeat tests gave the correct calls

[f] Samples with correct calls/samples tested

[g] Site 3: one sample had A260/A280 of 1.16 (1.6 is required), therefore only one sample was tested

[h] Site 1: one sample had A260/A280 of 1.46 (1.6 is required), therefore only two samples were tested

[i] Site 3: one sample had A260/A280 of 1.46 (1.6 is required), therefore only one sample was tested

[j] Site 3: one sample had A260/A280 of 1.45 (1.6 is required), therefore only one sample was tested

Table 4b Inter-Laboratory Reproducibility of the INFINITI CYP2C19 Assay by Sample

Sample ID	Genotype[a]	Replicates per sample	Replicates with Genotype Calls made by INFINITI[b]	Samples with Correct Calls[c]	Samples with No Calls[d]	Samples with Incorrect Calls[e]	Correct Call Rate[f] (%)	95% One-sided Confidence Lower Limit
1	*2/*2	40	38	37	2	1	92.5	83.1
2	*2/*2	40	35	35	5	0	87.5	76.0
3	*17/*17	40	39	39	1	0	97.5	91.4
4	*1/*17	40	37	37	3	0	92.5	83.1
5	*1/*3	40	40	40	0	0	100	98.8
6	*1/*2	40	40	40	0	0	100	98.8
7	*1/*2	40	40	40	0	0	100	98.8
8	*1/*1	30	29	29	1	0	96.7	88.6
9	*17/*17	30	29	29	1	0	96.7	88.6
10	*1/*1	40	40	40	0	0	100	98.8
11	*1/*17	30	29	29	1	0	96.7	88.6
12	*1/*2	20	20	20	0	0	100	97.5
All		**430**	**416**	**415**	**14**	**1**	**96.5**	**94.7**

[a] Determined by bi-directional sequencing. *1/*1 samples are wild-type for *2, *3 and *17

[b] Excludes samples with No Calls

[c] A sample with correct call indicates a correct call at all loci.

[d] One no call was due to Registration Spot Error - this error is reported when the microarray chip is not properly aligned. Repeat test gave the correct call; 13 reported NTCE Error - NTCE is reported if the quality or quantity of the DNA in the sample/PCR product is poor. Repeat tests gave the correct calls

[e] Initial result was incorrect (*1/*2 instead of *2/*2). The root cause of the incorrect call was not definitively determined

[f] Samples with correct calls/samples tested

Additional reproducibility studies were conducted at the same three sites to demonstrate the reproducibility of the INFINITI CYP2C19 Assay for additional samples including *2/*17 and *2/*3. The study involved three lots of the INFINITI CYP2C19 Assay. The sites ran identical samples comprised of six (6) genomic whole blood samples. The sites were blinded to sample identity. At each site, each sample was run in triplicate per day/operator for five non-consecutive days.

A total of 255 tests were completed. Overall correct call rate for the first time run was 97.6%. There were no incorrect calls. There were six no calls:

- One no call was due to Registration Spot Error - this error is reported when the microarray chip is not properly aligned.
- Five were due to NTCE error. NTCE is reported if the quality or quantity of the DNA in the sample/PCR product is poor. These NTCE errors might have been caused by temperature gradient during PCR, improper sealing of the PCR tubes, or operator pipetting error.

Results of the inter-laboratory reproducibility studies are summarized in Table 5a and Table 5b.

Table 5a Inter-Laboratory Reproducibility of the INFINITI CYP2C19 Assay by Genotype calls

Genotype[a]	Samples Tested	Site	Replicates per Site	Replicates with Genotype Calls made by INFINITI[b]	Correct Calls	Incorrect Calls	No Calls[c]	% Correct Calls[d]	95% One-sided Confidence Lower Limit
*1/*1	1	1	15	15	15	0	0	100	96.7
		2	15	15	15	0	0	100	96.7
		3	15	15	15	0	0	100	96.7
		Total	45	45	45	0	0	100	98.9
*1/*2	1	1	15	15	15	0	0	100	96.7
		2	15	15	15	0	0	100	96.7
		3	15	13	13	0	2	86.7	66.1
		Total	45	43	43	0	2	95.6	88.4
*1/*3	1	1[e]	0	n/a	n/a	n/a	n/a	n/a	n/a
		2	15	15	15	0	0	100	96.7
		3	15	15	15	0	0	100	96.7
		Total	30	30	30	0	0	100	98.3
*1/*17	1	1	15	15	15	0	0	100	96.7
		2	15	15	15	0	0	100	96.7
		3	15	15	15	0	0	100	96.7
		Total	45	45	45	0	0	100	98.9
*2/*3	1	1	15	15	15	0	0	100	96.7
		2	15	15	15	0	0	100	96.7
		3	15	12	12	0	3	80.0	56.4
		Total	45	42	42	0	3	93.3	84.9
*2/*17	1	1	15	15	15	0	0	100	96.7
		2	15	15	15	0	0	100	96.7
		3	15	14	14	0	1	93.3	77.4
		Total	45	44	44	0	1	97.8	92.4
Total	**6**	**All**	**255**	**249**	**249**	**0**	**6**	**97.6**	**95.6**

[a] Determined by bi-directional sequencing; *1/*1 samples are wild-type for *2, *3 and *17

[b] Excludes samples with No Calls

[c] One no call was due to Registration Spot Error - this error is reported when the microarray chip is not properly aligned; 5 reported NTCE Error - NTCE is reported if the quality or quantity of the DNA in the sample/PCR product is poor.

[d] Samples with correct calls/samples tested

[e] Site 1: DNA concentration was 8ng/µl, below the LOD of 10ng/µl, therefore no sample tested

Table 5b Inter-Laboratory Reproducibility of the INFINITI CYP2C19 Assay by Sample

Sample ID	Genotype[a]	Replicates per sample	Replicates with Genotype Calls made by INFINITI[b]	Correct Calls[c]	No Calls[d]	Incorrect Calls	Correct Call Rate[e] (%)	95% One-sided Confidence Lower Limit
1	*1/*3	30	30	30	0	0	100	98.3
2	*1/*17	45	45	45	0	0	100	98.9
3	*1/*1	45	45	45	0	0	100	98.9
4	*2/*17	45	44	44	1[b]	0	97.8	92.4
5	*2/*3	45	42	42	3	0	93.3	84.9
6	*1/*2	45	43	43	2	0	95.6	88.4
All		**255**	**249**	**249**	**6**	**0**	**97.6**	**95.6**

[a] Genotype determined by bi-directional sequencing; *1/*1 samples are wild-type for *2, *3 and *17

[b] Excludes samples with No Calls

[c] A sample with correct call indicates a correct call at all loci.

[d] One no call was due to Registration Spot Error - this error is reported when the microarray chip is not properly aligned; 5 reported NTCE Error - NTCE is reported if the quality or quantity of the DNA in the sample/PCR product is poor.

[e] Samples with correct calls/samples tested

Table 6 provides a summary of the combined reproducibility studies.

Table 6: Summary of the Inter-Laboratory Reproducibility of the INFINITI CYP2C19 Assay by Genotype calls

Genotype[a]	Samples Tested	Replicates per Sample	Replicates with Genotype Calls made by INFINITI[b]	Correct Calls[c]	No Calls[d]	Incorrect Calls[e]	Correct Call Rate[f] (%)	95% One-sided Confidence Lower Limit
*1/*1	3	115	114	114	1	0	99.1	97.0
*1/*2	4	145	143	143	2	0	98.6	96.4
*2/*2	2	80	73	72	7	1	90.0	82.8
*1/*3	2	70	70	70	0	0	100	99.3
*1/*17	3	115	110	110	5	0	95.7	915
*17/*17	2	70	69	69	1	0	98.6	95.1
*2/*3	1	45	42	42	3	0	93.3	84.9
*2/*17	1	45	44	44	1	0	97.8	92.4
Total	**18**	**685**	**665**	**664**	**20**	**1**	**96.9**	**95.6**

[a] Genotype determined by bi-directional sequencing; *1/*1 samples are wild-type for *2, *3 and *17
[b] Excludes samples with No Calls
[c] A sample with correct call indicates a correct call at all loci.
[d] Two no calls were due to Registration Spot Error - this error is reported when the microarray chip is not properly aligned; 18 reported NTCE Error - NTCE is reported if the quality or quantity of the DNA in the sample/PCR product is poor.
[e] Initial result was incorrect (*1/*2 instead of *2/*2). The root cause of the incorrect call was not definitively determined.
[f] Samples with correct calls/samples tested

Interference

Interference from potential interfering substances was evaluated using eight (8) whole blood samples. The potential interfering substances were added separately to the whole blood sample prior to DNA extraction and testing with the INFINITI CYP2C19 Assay. Genotype results were compared to those obtained from non-spiked samples. Sample genotype was verified by bi-directional DNA sequencing. The interference studies demonstrated that the INFINITI CYP2C19 Assay performance was not affected by the addition of the following substances.

Substance Added	Concentration
Bilirubin (conjugated)	60mg/dl
Bilirubin (unconjugated)	60mg/dl
Triglycerides (Intralipid)	3000mg/dl
Human albumin	6g/dl

No studies were conducted with oral anti-coagulants, and no claims are being made.

Sample Carry-Over

No sample carry-over was detected when 300ng of a positive sample was followed by 10ng of a second positive sample, and when 300ng of a positive sample was followed by a "No Template Control" or water. All genotype calls were 100% correct.

Reagent Stability

BioFilmChip Microarray: 12 months at RT (15 to 30°C)
Intellipac Reagent: 12 months Refrigerated (2 to 8°C)
Amplification Mix: 18 months Frozen (-30 to -15°C)

Conclusion The above pre-clinical and clinical data support the safety and effectiveness of the INFINITI CYP2C19 Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

AutoGenomics, Inc.
c/o Evelyn Lopez
Vice President, Regulatory Affairs
2980 Scott Street
Vista, CA 92081

OCT 25 2010

Re: k101683
Trade/Device Name: INFINITI CYP2C19 Assay
Regulation Number: 21 CFR §862.3360
Regulation Name: Drug Metabolizing Enzyme Genotyping System
Regulatory Class: Class II
Product Codes: NTI, NSU
Dated: October 6, 2010
Received: October 8, 2010

Dear Evelyn Lopez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

K101683

OCT 25 2010

510(k) Number (if known): K101683

Device Name: INFINITI®CYP2C19 Assay

Indications For Use: The INFINITI CYP2C19 Assay is an *in vitro* diagnostic test for the identification of a patient's CYP450 2C19 genotype in genomic deoxyribonucleic acid (DNA) obtained from EDTA-anticoagulated whole blood samples. The INFINITI CYP2C19 Assay is a qualitative assay for use in clinical laboratories upon prescription by the attending physician.

The INFINITI CYP2C19 Assay is indicated for use as an aid to clinicians in determining therapeutic strategy for therapeutics that are metabolized by the CYP450 2C19 gene product, specifically *2, *3, *17.

The INFINITI CYP2C19 Assay is not indicated to be used to predict drug response or non-response.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K101683